Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claims 1, 15-17, 20-22, 24, 37, 41, 45-48, 56, and 57 have been amended. Descriptive support for these amendments appears at page 13, lines 20-21 and 24-26 of the application, and original claims 13 and 14. Claims 13 and 14 have been cancelled without prejudice. No new matter has been added by way of these amendments. Claims 1-11, 15-33, 35, 37, 39-41, 43, and 45-60 remain pending. No excess claim fees are due with this response.

The rejection of claims 1-11, 15-26, 29-33, 35, 37, 39-41, 43, and 45-60 under 35 U.S.C. § 112 (first paragraph) for lack of written descriptive support is respectfully traversed in view of the above amendments.

Claims 1, 45, and 46 have been amended specifically to define the steroid hormone as "estradiol, progesterone, cortisol, corticosterone, estrone, testosterone or dihydroxytestosterone" and define the derivative as a progesterone derivative that is "11α-hydroxyprogesterone or 21-hydroxyprogesterone." These limitations appeared in claims 13 and 14, which were not rejected for lack of descriptive support but instead identified in the outstanding office action as allowable. Therefore, the amendments to claims 1, 45, and 46 overcome this basis of rejection.

For this reason, the written description rejection of claims 1-11, 15-26, 29-33, 35, 37, 39-41, 43, and 45-60 under 35 U.S.C. § 112 (first paragraph) should be withdrawn.

The rejection of claims 37 and 39-41 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed.

The PTO asserts that the specification, while being enabling for treating breast cancer and use of GnRH conjugate compounds as a veterinary contraceptive does not enable prevention of all cancers and infertility disorders.

Claims 37 has been amended to recite a "method of treating a hormone-dependent disease or condition" and claim 41 has been amended to recite a "method of treating infertility." Therefore, only therapeutic utilities are being claimed. The utility of the presently claimed compounds (i.e., conjugates) is premised on the previously known utility of GnRH analogues. As described at pages 1-3 of the present application, it was known in the prior art that GnRH

analogues have a range of clinical applications including treatment of hormone-dependent cancer, benign prostatic hypertrophy, endometriosis, uterine fibroids, premenstrual syndrome, polycystic ovarian syndrome, hirsutism, acne vulgaris, precocious puberty, acute intermittent porphyria, cryptoorchidism, delayed puberty and fertility treatment, as well as use as a contraceptive. This description of the known utility of GnRH analogues is consistent with that described in U.S. Patent No. 6,337,318 to Trigg et al. (filed September 01, 1997; issued January 8, 2002) (copy attached hereto as Exhibit 1), which recites that GnRH analogues have been used to treat endometriosis, leiomyoma, precocious puberty, hirsutism, uterine fibroids, cyclic auditory dysfunction, porphyria, benign prostatic hypertrophy, and sex hormone dependent tumors including breast cancer, ovarian cancer, and prostate cancer. Similarly, U.S. Patent No. 6,831,059 to Donovan (filed March 15, 2001; issued December 14, 2004) (copy attached hereto as Exhibit 2, Sequence Listing partially omitted), recites that GnRH antagonists and agonists have proven effective in the treatment of endometriosis, uterine fibroids, polycystic ovarian disease, precocious puberty and several gonadal steroid-dependent neoplasia, most notably cancers of the prostate, breast and ovary; and that these agents have been investigated as a contraceptive in both men and women, and in the treatment of pituitary gonadotroph adenomas, sleep disorders such as sleep apnea, irritable bowel syndrome, premenstrual syndrome, benign prostatic hyperplasia, and hirsutism.

Thus, given the known utility of GnRH analogues for treating the presently claimed conditions, the description of these conditions and the presently claimed conjugates, alone, is sufficient for enabling these treatments. That is because conjugation of the GnRH analogue to the steroid hormone or derivative extends the plasma half-life of the GnRH analogue, and improves the pharmacokinetics and pharmacodynamics of the GnRH analogue (*see* page 3, line 29 to page 4, line 22 of application). Persons of skill in the art would be fully able to identify preferred routes of delivery and dosage to obtain optimal activity of the claimed conjugates in treating these conditions.

For these reasons, the rejection of claims 37 and 39-41 under 35 U.S.C. § 112 (first paragraph) for lack of enablement should be withdrawn.

The rejection of claims 1-11, 15-26, 29-33, 35, 37, 39-41, 43, and 45-60 under 35 U.S.C. § 112 (second paragraph) for indefiniteness is respectfully traversed in view of the above amendments. Specifically, the amendments to Claims 1, 45, and 46 (to incorporate the

limitations from allowable claims 13 and 14) overcome the rejection of these claims. Therefore, the rejection of claims 1-11, 15-26, 29-33, 35, 37, 39-41, 43, and 45-60 under 35 U.S.C. § 112 (second paragraph) for indefiniteness should be withdrawn.

The objection to Claims 13, 14, 27, and 28 is rendered moot by the cancellation of claims 13 and 14, and the amendments to claim 1. The objection should be withdrawn.

In view of all the foregoing, it is submitted that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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